CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PFIZER INC

I. PREAMBLE

Pfizer Inc ("Pfizer") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and other legally binding authority of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"). Pfizer is a successor-in-interest to Warner-Lambert Company and its Parke-Davis Division. Pfizer has entered into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. Pfizer also will enter into settlement agreements with various States, and Pfizer's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA, Pfizer initiated certain voluntary compliance measures, which, as represented by Pfizer, include, among other things, the appointment of a Compliance Officer and designated compliance agents, the appointment of a Compliance Committee, a Disclosure Program, screening measures for Ineligible Persons, and regular training to Covered Persons concerning Pfizer's Code of Conduct. As further represented by Pfizer, the measures also include review and disciplinary measures aimed, in part, at ensuring that Pfizer's activities are: (i) in compliance with all Federal health care program requirements and (ii) meet Pfizer's goals of ensuring high ethical standards in the conduct of Pfizer's business practices.

Pfizer shall continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. Pfizer may modify its voluntary compliance measures as appropriate, but, at a minimum, Pfizer shall ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Pfizer under this CIA shall be five (5) years from the effective date of this CIA ("Effective Date") (unless otherwise specified). The Effective Date shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period of the CIA, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period".

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (A) Pfizer's final annual report; or (B) any additional materials submitted by Pfizer pursuant to OIG's request, whichever is later.

C. For purposes of this CIA, the term "Covered Persons" means:

1. all employees of the Pfizer Pharmaceuticals Group located in the United States whose job responsibilities directly relate to the promotion of prescription drug products to managed care entities (hereafter "Managed Care Contracting"). This group specifically consists of: a) all employees of the National Accounts Group and the National Healthcare Operations Group within the Healthcare Cluster; b) all employees who are members of the Managed Care Contracts Group (a sub-division of the Contracts Group); and c) those managers within the United States Pharmaceuticals ("USP") Finance Group to whom the members of the Managed Care Contracts Group directly report;

2. all employees of the Pfizer Pharmaceuticals Group whose job responsibilities directly relate to the gathering, calculation, verification or reporting of information for purposes of the Medicaid Rebate Program (codified at 42 U.S.C. § 1396r-8, et seq.) (hereafter, "Medicaid Rebate Related Functions"). This group specifically consists of: a) the employees who are members of the Government Contracting Group (a sub-division of the Contracts Group); and b) managers within the USP Finance Group to whom the members of the Government Contracting Group directly report;

3. those employees from the Corporate Legal Group whose job responsibilities directly relate to managed care entities, and all employees who are members of the Grants Committee; and

4. those persons of Pfizer's contract sales force whose job responsibilities directly relate to Managed Care Contracting.

Specifically excluded from this definition of "Covered Persons" are the personnel of entities with which Pfizer has agreements to co-promote its products. Pfizer shall, however, in good faith seek to obtain assurances that such persons have received appropriate training on proper promotional activities.

III. CORPORATE INTEGRITY OBLIGATIONS

Pfizer shall maintain a Compliance Program that, at a minimum, includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Pfizer presently has a Compliance Officer with responsibility for administering Pfizer's Compliance Program. Pfizer shall continue to employ an individual to serve as its Compliance Officer during the term of this CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Pfizer, shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcommittee, in such form or manner as the Board of Directors determines), and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Pfizer as well as for any reporting obligations created under this CIA.

Pfizer shall report to OIG, in writing, any changes in the identity of or any material changes in the position description of the Compliance Officer, or any material actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Pfizer currently has and shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as internal audit, regulatory affairs, sales/marketing, personnel, operations). The Compliance Officer shall chair the Compliance Committee, and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Pfizer shall report to OIG, in writing, any material changes in the composition of the Compliance Committee, or any material actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* Within 120 days of the Effective Date, Pfizer shall redistribute its Summary of Policies on Business Conduct (hereafter the "Blue Book") with an accompanying letter and have each Covered Person certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the letter and the Blue Book. Such letter shall state, at a minimum, the following items:

a. Pfizer's commitment to full compliance with all Federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its products in accordance with Federal health care program requirements;

b. Pfizer's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Pfizer's own Policies and Procedures (including the requirements of this CIA);

c. the requirement that all of Pfizer's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Pfizer (such as district managers or other supervisory personnel) suspected violations of any Federal health

care program requirements or of Pfizer's own Policies and Procedures;

d. the possible consequences to both Pfizer and Covered Persons of a failure to comply with Federal health care program requirements and with Pfizer's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and Pfizer's commitment to maintain confidentiality, as appropriate, and nonretaliation with respect to disclosures made in accordance with the terms of the Disclosure Program.

In addition, Pfizer shall revise and redistribute its Blue Book to all Covered Persons at the next scheduled printing of the Blue Book. The revised Blue Book shall include, at a minimum, the topics set forth in (a) through (e) above. Pfizer shall make the promotion of, and adherence to, the Blue Book an element in evaluating the performance of all Covered Persons.

New Covered Persons shall receive the Blue Book (and the accompanying letter, if before the next scheduled printing of the Blue Book) and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Pfizer shall annually review the Blue Book to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such materially revised Blue Book shall be distributed to Covered Persons within 30 days after finalizing (including printing) such changes. Each Covered Person shall certify that he or she has received, read, understood, and shall abide by the revised Blue Book within 30 days after the distribution of such revisions.

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Pfizer shall implement written Policies and Procedures regarding the operation of Pfizer's Compliance Program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Blue Book identified in Section III.B.1;

b. the methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services ("CMS") and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program; and

c. promotional practices that conform with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Pfizer shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any material revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on Pfizer's Intranet.

C. Training and Education.

1. *Training Requirements, General Description.* The training and education required under this section III.C. may be provided by supervisory employees, knowledgeable staff or Pfizer trainers and/or outside consultant trainers selected by Pfizer. Persons providing the training must be knowledgeable about the subject areas of their training.

Pfizer may provide the training required under this CIA through appropriate computer-based approaches. In that event, all applicable references to "hours" in this section III.C. shall mean "normative hours" as that term is used in the computer-based training industry. If Pfizer chooses to provide computer-based training, it shall also make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons who are receiving such training.

New Covered Persons shall receive the training outlined below in sections III.C.2. and III.C.3. within 30 days of the beginning of their employment or becoming Covered Persons, whichever is later. A Pfizer employee who has completed the training shall review a new Covered Person's work, to the extent that the work directly relates to Managed Care Contracting or Medicaid Rebate Related Functions until such time as the new Covered Person completes the applicable training.

Pfizer shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or IRO audits, and any other relevant information.

To the extent that Pfizer has provided training that satisfies the general or specific training requirements set forth below within 180 days prior to the Effective Date of this CIA, the OIG shall credit that training for purposes of satisfying Pfizer's training obligations for the first year of the CIA.

2. *General Training Provided to Covered Persons.* Within 120 days of the Effective Date of this CIA, Pfizer shall provide at least two hours of general training to each Covered Person. This general training, at a minimum, shall explain:

a. Pfizer's CIA requirements and Pfizer's Compliance Program (including the Blue Book and Policies and Procedures as they pertain to general compliance issues); and

b. in general, the proper methods of promoting, marketing and selling products to managed care entities; the need to calculate and report accurate information in connection with the Federal health care program requirements, including the Medicaid Rebate Program; and a general discussion of Pfizer's systems for gathering relevant data, and calculating and verifying information reported to CMS for purposes of the Medicaid Rebate Program.

After receiving the initial general training described above, each Covered Person shall receive at least one hour of general training annually.

3. *Specific Training for Relevant Covered Persons.* Within 120 days after the Effective Date, each Relevant Covered Person, as defined below, shall receive at least two hours of specific training in addition to the general training required above. After

receiving the initial specific training described in this Section, each Relevant Covered Person shall receive at least two hours of specific training annually.

a. Specific Training for Managed Care Relevant Covered Persons

"Managed Care Relevant Covered Persons" includes all employees in the National Accounts Group and the National Healthcare Operations Groups within the Healthcare Cluster; all employees who are members of the Managed Care Contracts Group (a sub-division of the Contracts Group); and those managers within the USP Finance Group to whom the members of the Managed Care Contracts Group directly report. The specific training for the Managed Care Relevant Covered Persons shall explain:

1. all applicable Federal health care program requirements (including the sanctions for violations) relating to Managed Care Contracting and Medicaid Rebate Related Functions (including, but not limited to, the Federal anti-kickback statute; the Civil Monetary Penalties law, 42 U.S.C. § 1320a-7a; the civil False Claims Act, 31 U.S.C. §§ 3729-3733; and the Medicaid Drug Rebate statute);

2. the personal obligation of each individual to comply with the legal requirements outlined above in section III.C.3.a.1.; and

3. examples of proper and improper Managed Care Contracting practices.

b. Specific Training for Medicaid Rebate Relevant Covered Persons

"Medicaid Rebate Relevant Covered Persons" includes the employees who are members of the Government Contracting Group (a sub-division of the Contracts Group); and managers within the USP Finance Group to whom the members of the Government Contracting Group directly report. The specific training for Medicaid Rebate Relevant Covered Persons shall explain:

1. in detail, Pfizer's systems for gathering relevant data and calculating, verifying and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Rebate Program, including the Government Pricing System ("GPS");

2. all applicable Federal health care program requirements (including the sanctions for violations) relating to Medicaid Rebate Related Functions (including the Medicaid Drug Rebate statute);

3. the personal obligation of each individual to comply with the applicable legal requirements outlined above in section III.C.3.b.2. and to fully track any variations identified within the GPS; and

4. examples of proper and improper practices related to Medicaid Rebate Related Functions.

4. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Engagement Procedures

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days after the Effective Date, Pfizer shall retain an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform Engagements to assist Pfizer in assessing and evaluating its systems, processes, policies and practices related to the Medicaid Rebate Program and to Managed Care Contracting. Each IRO retained by Pfizer shall have expertise in the requirements of the Medicaid Rebate Program and of Federal health care programs. Each IRO shall assess, along with Pfizer, whether it can perform the Engagements in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist.

The IRO shall conduct two types of engagements. One engagement shall address and analyze Pfizer's systems, processes, policies and

practices relating to the Medicaid Rebate Program ("Medicaid Rebate Engagement"). The second engagement shall address and analyze Pfizer's systems, policies and practices with regard to managed care contracting ("Managed Care Contracting Engagement").

b. Frequency of Engagements. If there are no material changes in Pfizer's Medicaid Rebate Program-related systems, processes, policies and practices during the term of the CIA, the IRO shall perform the Medicaid Rebate Engagement covering the first and fourth Reporting Periods. If Pfizer materially changes its systems, processes, policies and practices, then the IRO shall perform a Medicaid Rebate Engagement for the Reporting Period in which such changes were made in addition to conducting the Medicaid Rebate Engagement for the first and fourth Reporting Periods. The Managed Care Contracting Engagement shall be performed annually and shall cover each of the following periods (hereafter "Managed Care Contracting Review Periods"): 1) for the first year, December 1, 2002, through the first anniversary of the Effective Date of the CIA; and 2) for the remaining years of the CIA, each successive Reporting Period. The IRO shall perform all components of each of the engagements.

c. Retention of Records. The IRO and Pfizer shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Pfizer) related to the Engagements.

2. *Medicaid Rebate Engagement.* As more fully set forth in Attachment A, the Medicaid Rebate Engagement shall be an engagement that addresses Pfizer's systems, processes, policies and practices associated with the tracking, gathering, and accounting for all relevant data for purposes of appropriately calculating the Best Prices reported under the Medicaid Rebate Program.

3. Managed Care Contracting Engagement. The Managed Care Contracting Engagement shall review the Managed Care Related Expenditures paid to a sample of Managed Care Customers during the relevant Managed Care Contracting Review Period.

A "Managed Care Customer" is a for profit or not-for-profit entity: (a) whose principal business is managing or providing pharmacy and/or other healthcare benefits, including but not limited to health maintenance organizations, preferred provider organizations, and pharmacy benefit management companies; and (b) that has entered into a Discount Agreement with Pfizer that was in effect during the relevant Managed Care Contracting Review Period. The term "Managed Care Customer" does not include hospitals or health care providers.

A "Discount Agreement" is an agreement between Pfizer and a Managed Care Customer for discount payments made in connection with Pfizer pharmaceutical prescription products, and includes, but is not limited to, rebate agreements.

A "Managed Care Related Expenditure" is a payment by Pfizer to a Managed Care Customer made during the relevant Managed Care Contracting Review Period in connection with any corporate sponsorship or other promotional activities, including, but not limited to, the following types of activities: (a) speaker programs; (b) CME programs; (c) grants; (d) promotional or service programs (including, for example, speaker programs; patient information programs; sponsorship of booths or displays; co-promotion information; disease management programs; compliance programs; and informational presentations); and, (e) charitable contributions.

More specifically, for purposes of each Managed Care Contracting Engagement, the IRO shall randomly select a sample of 20 Managed Care Customers. The IRO shall then review the documentation for all Managed Care Related Expenditures for the 20 Managed Care Customers. If the IRO discovers Material Errors during its engagement, it shall conduct an Additional Engagement. All other applicable definitions, procedures, and reporting requirements for the Managed Care Contracting Engagement are outlined in Attachment A to this CIA, which is incorporated by reference.

The Managed Care Related Expenditures shall be reviewed based on the supporting documentation available at Pfizer or under Pfizer's control to determine whether all documentation required in connection with the Managed Care Related Expenditure exists and whether the documentation was completed in accordance with Pfizer's Policies and Procedures.

4. *Engagement Reports.* For each relevant Reporting Period, the IRO shall prepare a report (or reports) based upon the Medicaid Rebate Engagement and the Managed

Care Contracting Engagement performed (the "Engagement Report"). Information to be included in the Engagement Report is detailed in Attachment A.

5. *Validation Review.* In the event OIG has reason to believe that: (a) Pfizer's Medicaid Rebate Engagement or Managed Care Contracting Engagement fails to conform to the requirements of this CIA; or (b) the IRO's findings or the Engagement results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Medicaid Rebate Engagement or the Managed Care Contracting Engagement complied with the requirements of the CIA and/or the findings or Engagement results are inaccurate ("Validation Review"). Pfizer shall pay for the reasonable cost of any such Validation Review performed by OIG or any of its designated agents so long as it is initiated within one year after Pfizer's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Pfizer of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Pfizer may request a meeting with OIG to discuss the results of any Medicaid Rebate Engagement or Managed Care Contracting Engagement submissions or findings; present any additional or relevant information to clarify the results of either Engagement or to correct the inaccuracy of either Engagement; or propose alternatives to the proposed Validation Review. Pfizer shall provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Medicaid Rebate Engagement or Managed Care Contracting Engagement issue with Pfizer prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. *Independence/Objectivity Certification.* Pfizer shall undertake a good faith effort to obtain from the IRO a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Medicaid Rebate Engagement and the Managed Care Contracting Engagement and that it has concluded that it is, in fact, independent and/or objective, and the IRO shall include such certification in its report(s) to Pfizer. After undertaking good faith efforts to secure one, the failure to obtain an independence certification from the IRO shall not constitute a breach of this CIA (whether a material breach or otherwise) and shall not constitute a basis upon which the OIG may impose Stipulated Penalties; however, such a failure shall constitute a basis upon which the OIG may initiate a Validation Review, as described in section III.D.5 above, the costs of which shall be borne by Pfizer.

E. Disclosure Program.

Pfizer presently has a disclosure program designed to facilitate communications relating to compliance with Federal health care program requirements and Pfizer's policies (the "Disclosure Program"). During the term of this CIA, Pfizer shall maintain its Disclosure Program, which includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Pfizer's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law. During the term of the CIA, Pfizer shall continue to publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall continue to emphasize a non-retribution, non-retaliation policy, and shall continue to include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or his or her designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or the designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure all of the information necessary to determine whether a further review should be conducted has been obtained. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Pfizer shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or

nonprocurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

2. *Screening Requirements*. Pfizer shall not hire or contract with as a Covered Person any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Pfizer shall screen all prospective Covered Persons prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists shall hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement*. Within 90 days after the Effective Date, Pfizer shall review its list of current Covered Persons against the Exclusion Lists. Thereafter, Pfizer shall review its list of current Covered Persons against the Exclusion Lists annually. In addition, Pfizer shall require Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes the individual an Ineligible Person.

If Pfizer has actual notice that a Covered Person has become an Ineligible Person, Pfizer shall remove such person from responsibility for, or involvement with, Pfizer's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If Pfizer has actual notice that a Covered Person is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract term, Pfizer shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery by senior management at Pfizer's New York headquarters, Pfizer shall notify OIG, in writing, of any ongoing U.S.-based investigation known to Pfizer or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Pfizer has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Pfizer shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Pfizer establishes or acquires new business units engaged in Managed Care Contracting or Medicaid Rebate Related Functions, Pfizer shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of the establishment or acquisition. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider number (if any), and the corresponding contractor's name and address that has issued each provider number. All Covered Persons at each such business unit or location shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training). In the event that Pfizer acquires a pharmaceutical manufacturer within 120 days of the Effective Date of the CIA, nothing in this CIA shall apply to any Managed Care Contracting or Medicaid Rebate Related Functions of the acquired company until 90 days after the closing date of such acquisition.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Pfizer shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. a certification by the Compliance Officer that, to the best of his or her knowledge:

a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

b. all Covered Persons have completed the Blue Book certification required by Section III.B.1; and

c. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.

In the event that the Compliance Officer cannot certify to these items in their entirety, the Compliance Officer shall provide an explanation of any deficiencies and a timetable for when the deficiencies will be remedied. The documentation supporting this certification shall be available to OIG, upon request;

4. a description of the Disclosure Program required by Section III.E;

5. the identity of the IRO(s), a summary/description of all engagements between Pfizer and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and completion dates of the review conducted pursuant to Section III.D.

6. the certification from the IRO regarding its professional independence from and/or objectivity to Pfizer required by Section III.D.6;

7. a summary of personnel actions (other than hiring) taken pursuant to Section III.F.;

8. a list of all of Pfizer's locations (including locations and mailing addresses) which house Covered Persons, except for home offices the corresponding name under which each location is doing business, the

corresponding phone numbers and fax numbers, and, if applicable, each location's Federal health care program provider identification number(s) and the contractor's name and address to which Pfizer currently submits claims;

9. to the extent not already furnished to the OIG, or if modified, a description of Pfizer's corporate structure, including identification of any parent and sister companies, and subsidiaries, relevant to Managed Care Contracting or Medicaid Rebate Related Functions;

10. the certification required by Section V.C.

B. Annual Reports. Pfizer shall submit to the OIG Annual Reports with respect to the status of, and findings regarding, Pfizer's compliance activities for each of the five Reporting Periods.

Each Annual Report shall include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. the certification set forth in Attachment B to this CIA, and a certification by the Compliance Officer that, to the best of his or her knowledge:

a. all Covered Persons have completed any Blue Book certifications required by Section III.B.1.;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C; and

c. Pfizer has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the

Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs.

The documentation supporting this certification shall be available to OIG, upon request.

3. a copy of Pfizer's Blue Book required by Section III.B.1.;

4. a copy of all training materials used for the training required by Section III.C, a description of such training programs, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. (a) for the first Annual Report, a copy of all Policies and Procedures required by section III.B.2; and (b) for subsequent Annual Reports, a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in Federal health care program requirements) and copies of any such amended Policies and Procedures;

6. a complete copy of all reports prepared pursuant to the IRO's review, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

7. Pfizer's response and corrective action plan(s) related to any issues raised by the IRO(s);

8. a revised summary/description of all engagements between Pfizer and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

9. the certification from the IRO regarding its professional independence from and/or objectivity to Pfizer required by Section III.D.6;

10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;

11. a description of any personnel actions (other than hiring) taken by Pfizer as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F., and the actions taken in response to the obligations set forth in that Section;

12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

13. a description of all changes to the most recently provided list (as updated) of Pfizer's locations except home offices as required by Section V.A.8, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and, if applicable, each location's Federal health care program provider identification number(s) and the contractor name and address that issued each Medicare provider number; and

14. the certification required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, Pfizer is in compliance with all of the requirements of this CIA; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information therein is accurate and truthful.

D. Designation of Information. Pfizer shall clearly identify any portions of any of its submissions under this CIA that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Pfizer

shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, D.C. 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Pfizer

Douglas M. Lankler, Esq., Deputy Compliance Officer
Pfizer Inc
235 East 42nd Street (150/5/22)
New York, NY 10017
Phone: 212.733.3026
Fax: 212.464.7736

With a copy to:

Lynn Shapiro Snyder, Esq.
Epstein, Becker & Green, P.C.
1227 25th Street, N.W.
Washington, D.C. 20037
Phone: 202.861.0900
Fax: 202.296.2882

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means (such as Federal Express or its equivalent), provided that there is proof that such notification was received.

For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG Inspection, Audit and Review Rights

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of Pfizer's books, records, and other documents and supporting materials (to the extent such items are not protected under appropriately asserted legal privilege) and/or conduct on-site reviews of any of Pfizer's locations for the purpose of verifying and evaluating: (a) Pfizer's compliance with the terms of this CIA; and (b) Pfizer's compliance with the applicable requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Pfizer to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Pfizer's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Pfizer's employees shall have the right to be represented by counsel and any such employees may, at his or her option, be accompanied by counsel for Pfizer and/or their personal counsel at any interview by the OIG. Pfizer shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and Pfizer shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA. Pfizer's employees may elect to be interviewed with or without a representative of Pfizer present.

VIII. Document and Record Retention

Pfizer shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, for six years (or longer if otherwise required by law).

IX. DISCLOSURES

The OIG shall follow all applicable Federal laws concerning privacy and confidentiality, including the Federal Privacy Act, 5 U.S.C. §552a, to the greatest extent allowed by law. Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Pfizer prior to any release by OIG of information submitted by Pfizer pursuant to its obligations under this CIA and identified upon submission by Pfizer as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Pfizer shall have the rights set forth at 45 C.F.R. § 5.65(d). The OIG shall provide the pre-disclosure notice required pursuant to 45 C.F.R. §5.65(d) to the Compliance Officer at the address provided in section VI. Nothing in this CIA or any communication or report made pursuant to this CIA shall constitute or be construed as a waiver by Pfizer of Pfizer's attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect Pfizer's obligation to comply with the provisions of the CIA.

X. BREACH AND DEFAULT PROVISIONS

Pfizer is expected to fully and timely comply with all of its CIA obligations. A breach of this CIA does not constitute a breach of the Settlement Agreement between Pfizer and the United States or the settlement agreements with the individual States referred to in the Preamble. Any breach of the terms of those agreements does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. Section X of this CIA specifies all of the remedies available to the OIG if Pfizer fails to satisfy its obligations under this CIA. The remedies available to the OIG under this section X do not preempt or limit any actions that individual States may take against Pfizer under appropriate authorities.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Pfizer and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Pfizer fails to have in place any of the obligations described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. a Disclosure Program.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Pfizer fails to retain an IRO, as required in Section III.D.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Pfizer fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Pfizer hires or engages as a Covered Person an Ineligible Person and that person: (a) has responsibility for, or involvement with, Pfizer's business operations related to the Federal health care programs; or (b) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which Pfizer can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.F) as to the status of the person).

5. A Stipulated Penalty of $1,500 for each day Pfizer fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Pfizer fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day Pfizer fails to comply fully and adequately with any obligation of this CIA. In its notice to Pfizer, OIG shall state the specific grounds for its determination that Pfizer has failed to comply fully and

adequately with the CIA obligation(s) at issue and steps Pfizer shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Pfizer receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-5 of this Section.

B. Timely Written Requests for Extensions. Pfizer may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Pfizer fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Pfizer receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Pfizer has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Pfizer of: (a) Pfizer's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Pfizer shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Pfizer elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Pfizer cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one

of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Pfizer has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

c. a failure to retain and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Pfizer constitutes an independent basis for Pfizer's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Pfizer has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Pfizer of: (a) Pfizer's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Pfizer shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Pfizer is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Pfizer has begun to take action to cure the material breach; (ii) Pfizer is pursuing such action with due diligence; and (iii) Pfizer has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, Pfizer fails to satisfy the requirements of Section X.D.3, OIG may exclude Pfizer from participation in the Federal health care programs. OIG shall notify Pfizer in writing of its determination to exclude Pfizer (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. If, at the end of the period of exclusion, Pfizer wishes to apply for reinstatement, Pfizer shall submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to Pfizer of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Pfizer shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Pfizer was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Pfizer shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Pfizer to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Pfizer requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether Pfizer was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Pfizer had begun to take action to cure the material breach within that period; (ii) Pfizer has pursued and is pursuing such action with due diligence; and (iii) Pfizer provided to OIG within that period a reasonable timetable for curing the material breach and Pfizer has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Pfizer, only after a DAB decision in favor of OIG. Pfizer's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Pfizer upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Pfizer may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the

exclusion shall take effect 20 days after the DAB decision. Pfizer shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Pfizer, Pfizer shall be reinstated effective on the date of the original exclusion.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Pfizer and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Pfizer;

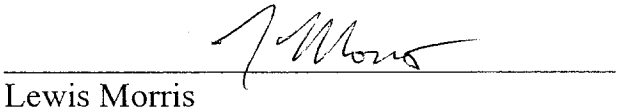
B. This CIA shall become final and binding on the Effective Date;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA and the CIA will be subject to modifications if so required by any change in Federal health care program requirements as referenced in the Preamble to this CIA;

D. The undersigned Pfizer signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



Lewis Morris
Chief Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

10/24/02
DATE

ON BEHALF OF PFIZER INC:

George W. Evans, Esq.
Heidi Chen, Esq.
Counsel for Warner-Lambert Company,
Parke-Davis and Pfizer Inc

10/24/02
DATE

Roger M. Sachs, Esq.
Douglas M. Lankler, Esq.
Counsel for Warner-Lambert Company,
Parke-Davis and Pfizer Inc

10/24/02
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Lynn Shapiro Snyder, Esq.
Stuart Gerson, Esq.
Wendy Goldstein, Esq.
Epstein Becker & Green, P.C.

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Lynn Shapiro Snyder 10/24/02

Lynn Shapiro Snyder, Esq.
Stuart Gerson, Esq.
Wendy Goldstein, Esq.
Epstein Becker & Green, P.C.

DATE

Attachment A to CIA for Pfizer Inc
Medicaid Rebate and Managed Care Contracting Engagements

I. IRO Engagements, General Description

As specified more fully below, Pfizer shall retain an Independent Review Organization ("IRO") to perform engagements to assist Pfizer in assessing and evaluating its systems, processes, policies and practices related to the Medicaid Rebate Program and to Managed Care Contracting. Pfizer may engage, at its discretion, a single entity to perform the Medicaid Rebate Engagements and the Managed Care Contracting Engagements, provided that the entity has the necessary expertise and capabilities to perform both.

The Medicaid Rebate Engagement shall be a review of Pfizer's systems, processes, policies and practices (including the controls on those systems, processes, policies and practices) as they relate to the Medicaid Rebate Program. If there are no material changes in Pfizer's systems, processes, policies and practices during the term of the CIA, the IRO shall perform the Medicaid Rebate Engagement covering the first and fourth Reporting Periods. If Pfizer materially changes its systems, processes, policies and practices as they relate to the Medicaid Rebate Program, the IRO shall perform a Medicaid Rebate Engagement covering the Reporting Period in which such changes were made in addition to conducting the Medicaid Rebate Engagement for the first and fourth Reporting Periods.

The Managed Care Contracting Engagement shall be a review of documentation relating to Managed Care Related Expenditures associated with a sample of 20 Managed Care Customers. The Managed Care Contracting Engagement shall be conducted annually and shall cover each of the following periods ("Managed Care Contracting Review Periods"): 1) for the first year of the CIA, December 1, 2002, through the first anniversary of the Effective Date of the CIA; and 2) for the remaining years of the CIA, each successive Reporting Period.

A. Medicaid Rebate Engagement

1. General Description of Medicaid Rebate Engagement

For at least the first and fourth Reporting Periods, the IRO shall review Pfizer's systems, processes, policies and practices associated with the tracking of, gathering of, and appropriate accounting for all data relevant for purposes of calculating the Best Prices reported to the Centers for Medicare and Medicaid Services ("CMS").

In general terms, the IRO shall review the following:

a) what systems, processes, policies, and practices are in place to track, gather, and appropriately account for those contract terms with Managed Care Customers that are relevant to the Medicaid Rebate Program. Specifically, this includes a review of:

1) the process used to determine whether discounts or rebates in Discount Agreements are included in the calculation of the Medicaid Best Price for any product (this includes: (a) a review of the data or information flow process by which relevant contract terms are included in or reflected in the calculation of the Medicaid Best Price; and (b) a review of any Pfizer inquiries to CMS regarding Medicaid Best Price and any responses to those inquiries);

2) the computer or accounting systems (e.g., the Government Pricing System ("GPS")) used to calculate the Medicaid Best Price; and

3) the policies and practices of the Government Contracts Group in examining GPS system reports for variations that require critical evaluation (including a review of the basis upon which variations are identified and the follow-up activities taken to identify the cause of the variations).

b) the effectiveness of the systems, processes, policies and practices to track, gather, and appropriately account for contract terms with Managed Care Customers that are relevant for Medicaid Rebate purposes (i.e., whether the systems, processes, policies and practices result in the inclusion of all appropriate and relevant contract terms in the calculation of the Medicaid Best Price).

2. Medicaid Rebate Engagement Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Medicaid Rebate Engagement. (This report may be combined with the report for the Managed Care Contracting Engagement.) Each report shall include the following items:

a) a description of the systems, processes, policies, and practices in place to track, gather, and appropriately account for those contract terms with Managed Care Customers that are relevant to the Medicaid Rebate Program;

b) a description of the documentation, information, and systems reviewed and the personnel interviewed, if any, including a description of Pfizer's inquiries to CMS regarding Medicaid Best Price and any responses to those inquiries; and

c) observations, findings, and recommendations on possible improvements to Pfizer's systems, processes, policies, and practices.

B. Managed Care Contracting Engagement

1. General Description of Managed Care Contracting Engagement

Pfizer's Policies and Procedures (referenced in section III.B.2. of the CIA) set forth certain requirements relating to promotional activities. For each Managed Care Contracting Review Period, the IRO shall examine the extent to which Area Managers are aware of Pfizer's policies and procedures relating to promotional activities directed at Managed Care Customers. For each Managed Care Contracting Review Period, the IRO also shall select and review Managed Care Related Expenditures to a randomly selected sample of 20 Managed Care Customers to assist Pfizer in assessing whether the requisite documentation relating to the Managed Care Related Expenditure exists and whether the documentation was completed in accordance with Pfizer's Policies and Procedures.

2. Initial Engagement

a. Selection of Documentation for Managed Care Related Expenditures

The IRO shall obtain from Pfizer a listing of all its Managed Care Customers for the relevant Managed Care Contracting Review Period and shall randomly select 20 of those customers as the basis for this Engagement. Specific to the identified 20 Managed Care Customers, the IRO shall review any Discount Agreement(s) and documentation related to Managed Care Related Expenditures ("Control Documentation"). For example, the Control Documentation could include any expense report or check request reflecting any such expenditure to Managed Care Customers; grant request letters and other grant-related documents; CME agreements; certifications for non-CME educational activities, etc.

The Discount Agreement(s) and Control Documentation associated with each of the 20 Managed Care Customers shall be treated as a separate universe for purposes of this Engagement.

The IRO shall review all Discount Agreement (s) and Control Documentation for all Managed Care Related Expenditures.

b. Attributes to Be Tested

During each Managed Care Contracting Review Period, the IRO shall review each universe to assess:

1. whether the appropriate and requisite Control Documentation exists in connection with each Managed Care Related Expenditure. This includes a review of whether all required supporting documentation (*e.g.*, receipts) and follow-up documentation (*e.g.*, progress and final reports produced in connection with grants) exist in accordance with Pfizer's Policies and Procedures;

2. whether the Discount Agreement(s) and Control Documentation were completed in accordance with the requirements set forth in Pfizer's Policies and Procedures. This includes a review of whether all required written approvals were obtained in accordance with Pfizer's Policies and Procedures; and,

3. whether any corrective action has been taken to comply with Pfizer's policies and procedures prior to IRO review of the relevant Managed Care Contracting Review Period.

The IRO shall review the Control Documentation using the criteria set forth above and shall identify any errors in the Control Documentation. The IRO shall identify both material and non-material errors in the Control Documentation. For purposes of the review, the Control Documentation will be found to have a Material Error if: 1) the appropriate and required Control Documentation does not exist and no corrective action has been taken prior to IRO review of the relevant Managed Care Contracting Review Period; or 2) information or data is omitted from key fields in the documentation that restricts the IRO's ability to understand the nature of the expenditure or activity and/or assess compliance with Pfizer's Policies and Procedures and no corrective action has been taken prior to IRO review of the relevant Managed Care Contracting Review Period. All other errors shall be considered non-material.

3. Additional Engagement if Material Errors Rates Are Discovered

In instances in which the IRO finds Material Errors, it shall conduct an Additional Engagement of the expenditures or activities reflected in the erroneous Control Documentation. The IRO shall perform this Additional Engagement in a manner designed to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the errors.

4. Documentation Engagement Report

The IRO shall annually prepare a report based upon each Managed Care Contracting Engagement performed. Each report shall include the following:

a. Elements to Be Included:

1. Managed Care Contracting Engagement Objectives: A clear statement of the objectives intended to be achieved by the review;

2. Engagement Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit and universe utilized in performing the procedures; and

3. Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Managed Care Contracting Engagement.

b. Results to Be Included:

The following results shall be included in each Managed Care Contracting Engagement Report:

1. for each universe of Control Documentation, the IRO shall describe, in general terms, the terms of any contract(s) and the types of expenditures made in connection with the Managed Care Customer during the Managed Care Contracting Review Period;

2. for each universe of Control Documentation, the IRO shall describe the procedures performed and state its findings and supporting rationale as to whether: a) appropriate and requisite Control Documentation exists in connection with each Managed Care Related Expenditure; and b) the Control Documentation was completed in accordance with the requirements set forth in Pfizer's Policies and Procedures;

3. for each universe of Control Documentation reviewed, the IRO shall identify all Material and non-material errors discovered. For the non-material errors, the IRO shall describe, in general terms, what the errors were. The IRO shall describe those situations when corrective action was taken prior to IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action;

4. if any Material Errors were discovered, the IRO shall describe the error and the Additional Engagement procedures it performed, and shall state its findings as to the root cause of the Material Errors; and

5. the findings regarding awareness of Area Managers of policies and procedures regarding promotional activities and a description of the methodology used to achieve those findings.

[Remainder of page intentionally left blank]

Attachment B

Certification for CIA with Pfizer Inc

CERTIFICATION

In accordance with the Corporate Integrity Agreement ("CIA") entered between Pfizer Inc (Pfizer) and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information and belief:

1) Pfizer has in place policies and procedures describing in all material respects the methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services ("CMS") and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program ("Medicaid Rebate Policies and Procedures");

2) the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with Pfizer's obligations under the Medicaid Drug Rebate Program; and,

3) Pfizer's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Best Price for Pfizer's products for each of the following four quarters: [identify each specific quarter.]

_____

Signature
[Insert Name and Title]
Compliance Officer

_____

Date